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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,568	09/30/2003	Trudce Klautky	11.030011US	7905

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VISTA IP LAW GROUP LLP
12930 Saratoga Avenue
Suite D-2
Saratoga, CA 95070

EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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06/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,568

Applicant(s)

KLAUTKY ET AL.

Examiner

Lyle A. Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/03;9/8/06</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach what a positive designator is and how one having ordinary skill in the art would determine if the claimed positive designator criteria are met. Additionally, the specification does not teach what method is performed to determine if acetic acid, reducing agent

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims do not describe what method steps are required to determine a positive indicator.

Claim 2 does not describe what method is intended by the intended assay.

Claim 3 does not describe what method is intended by the preparing a slide from the sample.

Claim 4 does not describe what method is intended to determine if sufficient cells are present.

Claim 5 does not describe what are a desired type of cells.

Claim 6 does not describe what positive designators are measured to determine if the sample is satisfactory for an automated slide preparation.

Claim 7 does not describe what method is used to determine adequate withdraw of the sample.

Claim 8 does not describe what method is performed to determine if an addition sample should be acquired.

Claim 9 does not describe what method is performed to determine if treatment is required.

Claims 12-13 and 15-17 do not describe the method to determine the criteria.

Claim 18 does not describe what the sample is mixed with.

Claim 22 does not describe what criteria are used to create the positive designator and how it is designated to electronic memory.

Claim 25 is not clear what method is performed to perform the method in "temporal conjunction".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Applicants admitted prior art on page 15 lines 1-12 of the original disclosure.

The Office has applied the 35 USC 102(b) statute based upon Applicants' disclosure of 5 patents pertaining the cited prior art that perform the claimed method. All of these patents would qualify as prior art under 35 USC 102(b) based upon their publication dates.

Applicants' state on page 15 in lines 1-12 "An apparatus performing a method of the invention" and proceed to state the names/patent numbers of the various apparatuses. The Office maintains all of the cited prior art teach methods of automatically classifying cytological sample that is indistinguishable from the instant claims.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Licha et al. (USP 6,258,340), EP 0573535 or Zahniser et al. (USP 5,168,066).

In light of the above 35 USC 112 issues, the invention is best understood as an automated cytology method using NIR.

Licha et al. teach a method using NIR, water soluble dyes and optical interrogation to determine the physiological properties of cytological samples. Column 8 teaches adding the dye to the tissues and irradiating the tissue with light in the range of 650-1200nm. The radiation that is not absorbed and the fluorescent radiation are electronically recorded by a CCD camera to produce a "synthetic image". The resultant

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"synthetic image" is recorded and compared against certain parameters to obtain a diagnosis. The claimed "optical interrogating" has been read on the taught "synthetic image". The claimed "attaching a positive designator to the sample attaching a manipulation designator" have been read on the taught steps of recording the "synthetic image" and comparison to certain parameters to obtain a diagnosis.

EP 0573535 teach in claims 1-10 a method of analysis of a biological specimen comprising irradiating the sample, detecting the emitted light with a CCD camera, storing the data and subsequent comparison to determine the physiological condition of the specimen. The claimed "optical interrogating" has been read on the taught storing the image. The claimed "attaching a positive designator to the sample attaching a manipulation designator" have been read on the taught steps of recording the image and subsequent comparison to certain parameters to obtain a diagnosis.

Zahniser et al. teach an automated method of cellular analysis using a thionin stain that contrast the cellular nuclear portion from the cytoplasm. The stained cell is subjected to IR and electronically imaged. The subsequent image is stored and compared to determine the diagnosis. The claimed "optical interrogating" has been read on the taught electronic imaging. The claimed "attaching a positive designator to the sample attaching a manipulation designator" have been read on the taught steps of recording the image and comparison to certain parameters to obtain a diagnosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
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